

caBIG Workspace Adopter Project Form

Adopters, please complete this form in advance of the caBIG kickoff meeting and return by e-mail to adamsm@mail.nih.gov. Completed forms will be made available to participants in advance of the meeting to enhance workspace discussions. During our conversations with you, we expressed the aspect of your program that we would like you to develop in the first year of the caBIG pilot; it is this we are asking you to address - here and in your presentation.

1. Sponsoring Cancer Center

Case Comprehensive Cancer Center

2. Workspace

Clinical Trials Management System

3. What "data" are you providing as adopters?

We have both regulatory and protocol specific information as well as patient information. The protocol specific and patient information occur in two separate and different databases. We are however, in the process of acquiring a new application that will include both a clinical trials management system as well as a patient data system. The cancer center database has over 450 protocols with over 5,000 patients in it.

4. What are the tools you envision would enhance the use and analysis of this "data"?

CDUS and Theradex reporting, SAE reporting.

5. What is your ability to evaluate the tools to be adopted?

We have a very small staff, but have the ability to work on projects that benefit the clinical trials management staff.

6. How will you provide system integration?

We currently have only a production environment set-up, however, we plan on adding a completely new development and production environment operational by 2nd quarter 2004.

7. How will you provide end-user testing?

That is a TDB.

8. How will you provide software validation?

Develop a set of rule-based testing methodologies based on industry testing standards, as well as developing specific standards.

9. What are your plans for interacting with the appropriate workspace developers?

Through traditional channels; phone, e-mail, fax, etc..